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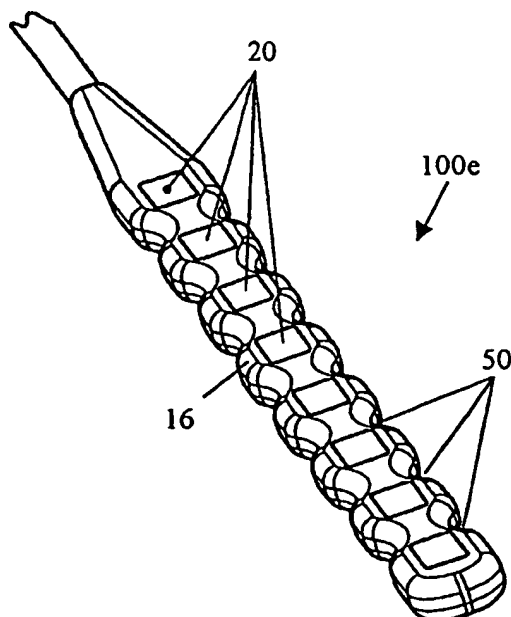
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(54) Title: STIMULATION/SENSING LEAD ADAPTED FOR PERCUTANEOUS INSERTION



(57) Abstract: The present invention relates to a percutaneous insertion-capable lead (100e), wherein insertion made through a percutaneous insertion structure. For one embodiment of such lead, the electrode-supporting stimulation portion (16) of the lead includes at least one flexible region (50), relative to a transverse dimension of the lead, to facilitate lead steerability.

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STIMULATION / SENSING LEAD ADAPTED FOR PERCUTANEOUS INSERTION

RELATED APPLICATION

[0001] This application is a continuation-in-part of United States Patent
5 Application No. 09/635,910, filed August 10, 2000, now pending.

FIELD OF THE INVENTION

[0002] The present invention relates to an epidural stimulation lead, and in particular, to an epidural stimulation lead adapted for percutaneous insertion.

BACKGROUND OF THE INVENTION

10 [0003] Application of specific electrical fields to spinal nerve roots, spinal cord, and other nerve bundles for the purpose of chronic pain control has been actively practiced since the 1960s. While a precise understanding of the interaction between the applied electrical energy and the nervous tissue is not fully appreciated, it is known that application of an electrical field to spinal nervous tissue (i.e., spinal nerve roots and
15 spinal cord bundles) can effectively mask certain types of pain transmitted from regions of the body associated with the stimulated tissue. More specifically, applying particularized electrical energy to the spinal cord associated with regions of the body afflicted with chronic pain can induce paresthesia, or a subjective sensation of numbness or tingling, in the afflicted bodily regions. This paresthesia can effectively
20 mask the transmission of non-acute pain sensations to the brain.

[0004] It is known that each exterior region, or each dermatome, of the human body is associated with a particular spinal nerve root at a particular longitudinal spinal position. The head and neck regions are associated with C2-C8, the back regions extend from C2-S3, the central diaphragm is associated with spinal nerve roots between
5 C3 and C5, the upper extremities correspond to C5 and T1, the thoracic wall extends from T1 to T11, the peripheral diaphragm is between T6 and T11, the abdominal wall is associated with T6-L1, the lower extremities are located from L2 to S2, and the perineum from L4 to S4. By example, to address chronic pain sensations that commonly focus on the lower back and lower extremities, a specific energy field can
10 usually be applied to a region between bony level T8 and T10. As should be understood, successful pain management and the avoidance of stimulation in unafflicted regions necessarily requires the applied electric field to be properly positioned longitudinally along the dorsal column.

[0005] Positioning of an applied electrical field relative to a physiological midline
15 is equally important. Nerve fibers relating to certain peripheral areas extend between the brain and a nerve root along the same relative side of the dorsal column as the corresponding peripheral areas. Pain that is concentrated on only one side of the body is "unilateral" in nature. To address unilateral pain, electrical energy is applied to neural structures on the side of a dorsal column that directly corresponds to a side of the body
20 subject to pain. Pain that is present on both sides of a patient is "bilateral." Accordingly, bilateral pain is addressed through either an application of electrical energy along a patient's physiological midline or an application of electrical energy that transverses the physiological midline.

[0006] Pain-managing electrical energy is commonly delivered through electrodes positioned external to the dura layer surrounding the spinal cord. The electrodes are carried by two primary vehicles: a percutaneous catheter and a laminotomy lead.

5 **[0007]** Percutaneous catheters, or percutaneous leads, commonly have a circular cross-section (~0.05 inches) and three or more, equally-spaced ring electrodes. Percutaneous leads are placed above the dura layer of a patient using a Touhy-like needle. For insertion, the Touhy-like needle is passed through the skin, between desired vertebrae, to open above the dura layer. For unilateral pain, percutaneous
10 leads are positioned on a side of a dorsal column corresponding to the "afflicted" side of the body, as discussed above, and for bilateral pain, a single percutaneous lead is positioned along the patient midline (or two or more leads are positioned on each side of the midline).

[0008] Laminotomy leads have a paddle configuration and typically possess a
15 plurality of electrodes (for example, two, four, eight, or sixteen) arranged in one or more columns. An example of a sixteen-electrode laminotomy lead is shown in Figure 1. Using the laminotomy lead of Figure 1 as but one example, the paddle portion of the laminotomy lead is approximately 0.4 inches wide and a thickness of approximately 0.065 inches. Common to laminotomy leads, the exposed surface area of the plurality
20 of electrodes is confined to only one surface of the laminotomy lead, thus facilitating a more focused application of electrical energy.

[0009] It is typical that implanted laminotomy leads are transversely centered over the physiological midline of a patient. In such position, multiple columns of electrodes are well suited to address both unilateral and bilateral pain, where electrical energy may be administered using either column independently (on either side of the midline) or administered using both columns to create an electric field which traverses the midline. A multi-column laminotomy lead enables reliable positioning of a plurality of electrodes, and in particular, a plurality of electrode columns that do not readily deviate from an initial implantation position.

[0010] Given the relative dimensions of conventional laminotomy leads, a surgical procedure is necessary for implantation. The surgical procedure, or partial laminectomy, requires the resection and removal of certain vertebral tissue to allow both access to the dura and proper positioning of a laminotomy lead. The laminotomy lead offers a more stable platform, which is further capable of being sutured in place, that tends to migrate less in the operating environment of the human body.

[0011] Percutaneous leads require a less-invasive implantation method and, with a plurality of leads, provide a user the ability to create almost any electrode array. While laminotomy leads are likely more stable during use, these leads do not offer an opportunity for electrode array variance as the configuration of such arrays are fixed.

[0012] To supply suitable pain-managing electrical energy, stimulation leads are connected to multi-programmable stimulation systems, or energy sources (not shown). Typically, such systems enable each electrode of a connected stimulation lead to be set as an anode (+), a cathode (-), or in an OFF-state. As is well known, an electric current

"flows" from an anode to a cathode. Consequently, using the laminotomy lead of Figure 1 as an example, a range of very simple to very complex electric fields can be created by defining different electrodes in various combinations of (+), (-), and OFF. Of course, in any instance, a functional combination must include at least one anode and at least
5 one cathode.

[0013] Notwithstanding the range of electric fields that are possible with conventional stimulation leads, in certain instances it is necessary to concentrate electrical energy at a particular point, or over a small region. As an example of such occasion, assume pain-managing electrical energy is applied at or about T8 to address
10 only localized lower back pain. At T8, however, spinal nervous tissue corresponding to the patient's lower extremities commingles with the specific spinal nervous tissue associated with the lower back. Moreover, it is common that the lower back-related spinal nervous tissue is deeply embedded within the combined spinal nervous tissue. It is thus desirable to focus applied electrical energy to the targeted nervous tissue to (i)
15 reach the deeply situated target nervous tissue and (ii) avoid undesirable stimulation of unafflicted regions.

[0014] Accordingly, a need exists for a percutaneously insertable stimulation lead that facilitates an application of delivered electrical energy in a manner consistent with that delivered through conventional laminotomy leads.

20 **SUMMARY OF THE INVENTION**

[0015] At least one aspect of the present invention is drawn to a stimulation lead having a plurality of electrodes, a plurality of terminals, and a plurality of conductors,

wherein a conductor of the plurality of conductors electrically couples one terminal of the plurality of terminals with at least one electrode of the plurality of electrodes.

Although this lead is adapted to pass through a percutaneous introduction device for insertion into a human body, the lead includes a body defining a paddle structure that is substantially defined by two principal opposing planar surfaces. One of the two planar surfaces incorporate the plurality of electrodes; however, a greatest transverse dimension of the body is less than a corresponding interior dimension of a percutaneous introduction device used for insertion of the lead into a human body.

[0016] Another aspect of the present invention includes providing the body of the lead with at least one waisted region that effectively increases the flexibility of the body.

[0017] Another aspect of the present invention is drawn to a method of placing a lead in a human patient. This method concerns providing a lead, percutaneously accessing a site proximate to a desired lead placement site through formation of an access passage, and directing the lead through the access passage to the desired lead placement site. The lead includes a body having two principal surfaces arranged opposite to one another, each of such surfaces being substantially planar, and at least one waisted region; a plurality of terminals; a plurality of electrodes positioned relative to one principal surface of the body; and a plurality of conductors. A conductor electrically couples one terminal of the plurality of terminals with at least one electrode.

[0018] An object of the present invention is to provide a paddle-type lead, capable of either delivering stimulation or sensing electrical activity, which includes a

plurality of electrodes but is adapted to be inserted and positioned within a human body via percutaneous access.

5 **[0019]** Another object of the present invention is to provide a paddle-type lead that includes certain features to increase the flexibility of such lead, thus enhancing the steerability of such lead.

[0020] Other objects and advantages of the present invention will be apparent to those of ordinary skill in the art having reference to the following specification together with the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

10 **[0021]** In the drawings, like reference numerals and letters indicate corresponding parts throughout the several views:

Figure 1 is a plan view of a conventional laminotomy spinal cord stimulation lead;

15 Figure 2 is a plan view of a laminotomy spinal cord stimulation lead that illustrates the fundamental principle of construction of one aspect of the present invention;

Figure 3 is a plan view of a first embodiment of a laminotomy spinal cord stimulation lead in accordance with one aspect of the present invention;

Figure 4 is a plan view of a second embodiment of a laminotomy spinal cord stimulation lead in accordance with one aspect of the present invention;

Figure 5 is a plan view of a third embodiment of a laminotomy spinal cord stimulation lead in accordance with one aspect of the present invention;

Figure 6 illustrates a percutaneous implantation of the laminotomy spinal cord stimulation lead of Figure 3;

5 Figure 7A illustrates a lower surface of another embodiment of a percutaneous laminotomy lead in accordance with the present invention, Figure 7B is a plan view of the percutaneous laminotomy lead of Figure 7A, and Figure 7C is a perspective view of the percutaneous laminotomy lead of Figures 7A and 7B;

10 Figure 8A illustrates a straight stylet for placement within a passage formed within the percutaneous laminotomy leads of the present invention, and Figure 8B illustrates a bent stylet also for placement within a passage formed within the percutaneous laminotomy leads of the present invention;

15 Figures 9A, 9B, and 9C illustrate a functional relationship between the bent stylet of Figure 8A and the percutaneous laminotomy leads of at least one of Figures 7B, 10A, and 11;

Figure 10A is a plan view of another embodiment of a percutaneous laminotomy lead in accordance with the present invention, and Figure 10B is a cross-sectional view of the percutaneous laminotomy lead of Figure 10A as taken along line I-I;

20 Figure 11 is a plan view of another embodiment of a percutaneous laminotomy lead in accordance with the present invention;

Figure 12 is a plan view of another embodiment of percutaneous laminotomy lead in accordance with the present invention;

Figure 13A is a plan view of an insertion needle-insertion stylet combination for facilitating the implantation of a percutaneous laminotomy lead, Figure 13B illustrates a
5 side view of the insertion needle-stylet of Figure 13A, and Figure 13C is a partial perspective view of the insertion needle-stylet combination of Figures 13A and 13B;

Figure 14 is a cross-sectional view of the insertion needle-stylet combination of Figure 13A as taken along line II-II;

Figure 15 is a cross-sectional view of the insertion needle-stylet combination of
10 Figure 13A as taken along line III-III; and

Figure 16 illustrates a potential placement relationship using multiple percutaneous laminotomy leads, wherein the illustrated leads are of the form illustrated in Figure 7A.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

15 [0022] Various embodiments, including preferred embodiments, will now be described in detail below with reference to the drawings.

[0023] In reference to Figure 1, the illustrated laminotomy lead 10 includes a proximal end 12 and a distal end 14. The proximal end 12 includes a plurality of electrically conductive terminals 18, and the distal end 14 includes a plurality of
20 electrically conductive electrodes 20 arranged within a flat, thin paddle-like structure 16.

Typically, each terminal 18 is electrically connected to a single electrode 20 via a conductor 22; however, a terminal 18 can be connected to two or more electrodes 20.

[0024] Terminals 18 and electrodes 20 are preferably formed of a non-corrosive, highly conductive material. Examples of such material include stainless steel, MP35N, platinum, and platinum alloys. In a preferred embodiment, terminals 18 and electrodes 20 are formed of a platinum-iridium alloy.

[0025] The sheaths 24 and the paddle structure 16 are formed from a medical grade, substantially inert material, for example, polyurethane, silicone, or the like. Importantly, such material must be non-reactive to the environment of the human body, provide a flexible and durable (i.e., fatigue resistant) exterior structure for the components of lead 10, and insulate adjacent terminals 18 and/or electrodes 20. Additional structure (e.g., a nylon mesh, a fiberglass substrate) (not shown) can be internalized within the paddle structure 16 to increase its overall rigidity and/or to cause the paddle structure 16 to assume a prescribed cross-sectional form (e.g., a prescribed arc along a transverse direction of the paddle structure 16) (not shown).

[0026] The conductors 22 are carried in sheaths 24. In the illustrated example, each sheath 24 carries eight (8) conductors 22. Given the number of conductors 22 that are typically carried within each sheath 24, the cross-sectional area of each conductor 22 is restricted. As but one example, for a sheath 24 in accordance with the present invention, having an outer diameter of approximately 0.055 inches, each conductor 22 would be approximately 0.0065 inches in diameter.

[0027] Each conductor 22 is formed of a conductive material that exhibits desired mechanical properties of low resistance, corrosion resistance, flexibility, and strength.

While conventional stranded bundles of stainless steel, MP35N, platinum, platinum-iridium alloy, drawn-brazed silver (DBS) or the like can be used, a preferred

5 embodiment of the present invention uses conductors 22 formed of multi-strands of drawn-filled tubes (DFT). Each strand is formed of a low resistance material and is encased in a high strength material (preferably, metal). A selected number of "sub-strands" are wound and coated with an insulative material. With regard to the operating environment of the present invention, such insulative material would protect each

10 individual conductor 22 if its respective sheath 24 were to be breached during use.

Wire formed of multi-strands of drawn-filled tubes to form conductors 22, as discussed here, is available from TempFlex Cable, Inc.

[0028] In addition to providing the requisite strength, flexibility, and resistance to fatigue, conductors 22 formed of multi-strands of drawn-filled tubes, in accordance with

15 the above description, provide a low resistance alternative to other conventional materials. Specifically, a stranded wire, or even a coiled wire, having a length of approximately 60 cm and formed of MP35N or stainless steel or the like would have a measured resistance in excess of 30 ohms. In contrast, for the same length, a wire formed of multi-strands of drawn-filled tubes could have a resistance less than 4 ohms.

20 Accordingly, in a preferred embodiment, each conductor 22, having a length equal to or less than 60 cm, has a resistance of less than 25 ohms. In a more preferred embodiment, each conductor 20, having a length equal to or less than 60 cm, has a resistance equal to or less than 10 ohms. In a most preferred embodiment, each

conductor 20, having a length equal to or less than 60 cm, has a resistance of less than 4 ohms.

[0029] While a number of material and construction options have been discussed above, it should be noted that neither the materials selected nor a construction

5 methodology is critical to the present invention.

[0030] The following discussion is directed to a number of examples illustrated in Figures 2-5. While the examples set forth a variety of variations of the present invention, it may be readily appreciated that the present invention could take any of a variety of forms and include any number of electrodes. Importantly, however, the

10 present invention is characterized by a first electrode, or a first electrode array, that substantially encompasses or circumscribes at least one independently controlled electrode. The first electrode (or first electrode array) can operatively form an "anode guard" relative to the substantially surrounded independently controlled electrode(s). To clarify such structure, the following examples are provided.

15 **[0031]** Figure 2 illustrates a laminotomy lead 100a featuring the fundamental principle of construction of the present invention. Specifically, the paddle structure 16 includes a plurality of electrodes 20, wherein one electrode 30 substantially surrounds another electrode 40. For this embodiment, each electrode is electrically coupled to an independent terminal (not shown), which is connectable to a programmable energy

20 source, for example, a pulse generator (not shown). The construction and arrangement of the terminals (and related conductors, which establish the desired electrical coupling) are not in themselves unique but are consistent with that described hereinabove.

[0032] Depending upon a configuration/programmability of the energy source connected to the laminotomy lead 100a, either the electrode 30 or the electrode 40 could operatively assume a positive polarity (with the remaining electrode assuming a negative polarity) during active delivery of electrical energy therefrom. For purposes of
5 focusing applied electrical energy, however, the electrode 30 assumes a positive polarity, whereby in such a condition the electrode 30 forms an "anode guard" relative to the encompassed electrode 40.

[0033] The electrode 30 can be constructed in a manner and from a material consistent with that used to form electrode 40. Alternatively, as longitudinal and
10 transverse flexibility of the paddle structure 16 are desirable, it is preferred that the electrode(s) 30 be formed so as to not otherwise significantly impair the inherent flexibility of the paddle structure 16. Accordingly, the electrode 30 can be constructed using less material--in a thickness direction--than an electrode 40, formed from a
15 conductive film/foil applied to the surface of the paddle structure 16, formed through deposition of conductive material, constructed using a coil (Figure 3), or formed using
other like processes/techniques that are well known in the art.

[0034] An anode guard functions, in part, to laterally limit an applied electrical field, which assists in reducing extraneous stimulation of surrounding neural tissue. In this regard, neural tissue at or immediately about the cathode electrode(s) is
20 depolarized, while neural tissue relative to the anode guard is subject to hyperpolarization. Further, an anode guard in accordance with that illustrated in Figure 2 focuses an applied electrical field from practically every direction to any cathode-electrode(s) positioned therein. Thus, for any given drive signal from a coupled energy

source, the stimulation lead of the present invention can effect a deeper application of applied energy than stimulation leads of a conventional nature.

[0035] Figure 3 illustrates a four-channel (a "channel" represents a controllable electrical output) laminotomy stimulation lead 100b in accordance with the present invention. The stimulation lead 100b is shown having a plurality of electrodes 20, which includes an electrode 30, formed from a coil, that substantially circumscribes an electrode array formed of three electrodes 40a, 40b, and 40c.

[0036] Again, while each of the plurality of electrodes 20 could individually function as a cathode or an anode, or be placed in an OFF-state, it is intended that the electrode 30, as an anode guard, assume a positive polarity. To this end, the form of an electric field generated using the electrode 30 is altered/controlled through setting each of the electrodes 40a, 40b, and 40c as a cathode, an anode, or in an OFF-state. Such control over the electrodes 40a, 40b, and 40c enables formation of a focused electrical field with a single electrode 40 as a cathode or a more diverse electrical field spread over two or more electrodes 40, whereas each electrode 40 of such plurality functions as a cathode.

[0037] Furthermore, to the extent that the benefits of an anode guard are not required, the electrode 30 may be placed in an OFF-state. In such operative configuration, the laminotomy lead 100b then functions in a manner consistent with conventional laminotomy stimulation leads.

[0038] The configuration illustrated in at least Figure 3 enables the delivery of electrical energy to targeted nervous tissue with fewer required electrodes. Moreover, it

should be noted that the compact structure (i.e., narrow transverse dimension) of the laminotomy lead 100b enables such laminotomy lead to be implanted percutaneously, if so desired, using a special insertion needle 200 (Figure 6) that accommodates the larger dimensions (relative to a conventional percutaneous lead) of the laminotomy lead 100b. Of note, additional embodiments of this variation are described below in cooperation with Figures 7 and 10-12.

[0039] Figure 4 illustrates a laminotomy stimulation lead 100c in accordance with the present invention. The stimulation lead 100c includes a plurality of electrodes 20, which includes a first electrode array having a plurality of electrodes 30a-30d that substantially surrounds a second electrode array having a plurality of electrodes 40.

[0040] Similar to the stimulation lead 100b, the second electrode array of the stimulation lead 100c is formed of a group of individual electrodes that can respectively beset as an anode, a cathode, or in an OFF-state. Although the electrodes 40 of the stimulation lead 100c are shown in two, staggered columns, the arrangement of the electrodes 40 of the second electrode array is not critical to the present invention--the electrodes 40 of the second electrode array may assume any multiple-column arrangement.

[0041] Unlike the other embodiments illustrated, the anode guard is constructed of a first electrode array that includes electrodes 30a-30d. In a preferred embodiment, each electrode of the first electrode array extends for a length substantially equivalent to a comparable dimension of at least two of electrodes 40 of the second electrode array. Further, and generally consistent with the structures of Figures 2, 3, and 5, the

collection of electrodes 30a-30d forms an effectively continuous ring that substantially extends about the second electrode array.

[0042] Although each of the electrodes 30a-30d may be electrically independent (i.e., coupled to respective conductors/terminals), allowing each respective electrode to be an anode, a cathode, or set to an OFF-state, in consideration of practical space limitations, it may be advisable to electrically couple two or more of electrodes 30a-30d. In a simplest form, electrodes 30a-30d are electrically linked so as to maintain the same electrical state during operation and minimize the number of conductors necessary to couple the first electrode array to an energy source:

[0043] Depending upon the form/construction of the electrodes 30a-30d, the segmented nature of the illustrated first electrode array of this embodiment would improve longitudinal flexibility of the paddle structure 16. As additional segmentation of electrodes 30b and 30d would likewise improve transverse flexibility of the paddle structure 16, such modification is within the scope of this embodiment of the present invention.

[0044] To maintain a generally uniform electrical field between an anode guard and one or more cathode-electrodes, the distance between the one or more cathode-electrodes and the anode guard should be largely equidistant. Achieving this optimum arrangement is typically hindered by both a need that the platform structure 16 fit easily within the narrow confines of the human epidural space and a desire that the provided electrode array(s) span a significant vertebral range of spinal nervous tissue.

[0045] While a long electrode array substantially surrounded by a single anode guard electrode (or a composite anode guard) would not be operatively ineffective, an alternative to such structure is illustrated by the stimulation lead 100d of Figure 5. Specifically, the electrodes 40 can be divided into groups 40a and 40b, and each electrode group 40a and 40b is encompassed by its own independently controlled anode guard electrode 30a and 30b.

[0046] In furtherance of the percutaneous implantation method illustrated in Figure 6, another embodiment of a percutaneous lead 100e is illustrated in Figures 7a-7c. The percutaneous lead 100e is a "laminotomy" lead which can have the anode guard construction or it can be a non-anode guard-bearing percutaneous lead. Consistent with conventional laminotomy leads, the stimulation lead 100e includes two principal, substantially planar surfaces, one of which carries the plurality of electrodes 20. Unique to the percutaneous insertion-capable lead of the present invention, the greatest transverse dimension (i.e., the width dimension) of the stimulation lead 100e is preferably about 75% of a width dimension of a conventional laminotomy lead, more preferably about 50% of a width dimension of a conventional laminotomy lead, and most preferably about 40% of a width dimension of a conventional laminotomy lead. Notwithstanding these preferences, the greatest width dimension of the percutaneous laminotomy lead of the present invention can be between about 20% and 40% of a conventional laminotomy lead. Further yet, it is preferable that the greatest transverse dimension of the platform structure 16 is substantially equivalent to two times (2x) the thickness of the same.

[0047] The limiting factor for a minimum width dimension of the percutaneous laminotomy lead of this invention is a maximum transverse dimension of any given electrode 20, wherein each electrode must possess adequate surface area to effectively deliver sufficient electrical energy or sense environmental conditions.

5 [0048] The stimulation lead 100e includes necked portions 50, or "waisted" regions, wherein a transverse dimension at the necked portions 50 is less than an adjacent (e.g., maximum) transverse dimension of the platform structure 16. This structural configuration creates a stimulation lead having a varying cross-sectional moment of inertia, which enables a predetermined flexibility in a plane substantially
10 parallel to the principal planar surfaces of the platform structure 16. Improving the flexibility of the stimulation leads in this matter enhances the steerability of such stimulation leads.

[0049] As shown in Figures 7A and 10B, a channel 52 longitudinally extends through stimulation lead 100e (Figures 7A and 10B). The channel 52 is adapted to
15 receive a stylet 54.

[0050] Figures 8A and 8B illustrate two configurations for a stylet. Figure 8A illustrates a stylet 54 having a straight distal end. If used with the stimulation lead 100e, this stylet 54 would enable forward driving of the stimulation lead/stylet combination but would not offer an optimum structure to readily alter a course of (i.e., steer) the
20 stimulation lead 100e from a particular course. Conversely, Figure 8B illustrates a stylet 54a having a bent (i.e., contoured) distal end. If used with the stimulation lead 100e, this stylet 54a would enable forward driving of the stimulation lead/stylet combination

(Figure 9B, when the contoured end of the stylet 54a is oriented substantially perpendicular to the principal planar surfaces of the stimulation lead 100e) as well as directional steering. In reference to Figures 9A and 9C, when the contoured end of the stylet 54a is oriented substantially parallel to the principal planar surfaces of the stimulation lead 100e, the stimulation lead 100e deforms in a direction consistent with a predetermined direction of the bent end of the stylet 54a. Accordingly, through rotation of a bent stylet 54a, a practitioner can purposely control and direct the stimulation lead being implanted to a desired site. Thus the combination of the curved stylet 54a and the stimulation lead 100e provides a stylet steerable, electric field directional, percutaneous stimulation lead. With either the straight stylet 54 or the curved stylet 54a, the insertion of the stylet into the inner lumen the entire length of the lead provides a stiffening member for handling and placing the lead.

[0051] While the bent stylet 54 of Figure 8B is illustrated in one particular form, it should be readily appreciated that the contour could take any of a number of forms. In particular, the distal end of the illustrated stylet 54 could be formed so as to have a gentle bow (not shown) or include additional angles (not shown) that could heighten the nature of the deflection of the platform structure 16 when the stylet 54 is properly oriented.

[0052] It is anticipated that the handle 56 of the stylet 54 would include a marking or the like (not shown) to indicate to the user a contour direction, if any, of the stylet 54.

[0053] For this embodiment, the stimulation lead 100e includes a serial arrangement of waisted regions 50 that repeat along substantially an entire length of the

platform structure 16 so as to maximize the flexibility of the stimulation lead 100e. In addition to adding flexibility to the platform structure 16, the scalloped edge of at least the stimulation lead 100e enables multiple stimulation leads to be operatively positioned relative to one another (Figure 16) in close proximity. In this instance, multiple
5 stimulation leads can be combined to effectively produce a structure akin to a conventional, non-percutaneous laminotomy lead like that illustrated in Figure 1.

[0054] Figure 10A illustrates a stimulation lead 100f that includes a single waisted region 50. The stimulation lead 100f would operatively exhibit performance characteristics like the stimulation lead 100e; however, the overall flexibility of the
10 platform structure 16 would be arguably less. Depending upon the nature of the procedure to be performed or the environment to which a percutaneous laminotomy stimulation lead is to be inserted, it may be that the stimulation lead 100f may be more suitable than the stimulation lead 100e. Moreover, while the stimulation leads 100e and 100f represent two extremes of this design, it is contemplated that any number of
15 waisted regions 50 can be used for a stimulation lead depending upon a desired level of planar flexibility. To this end, an alternative design 100g is further illustrated in Figure 11.

[0055] Figure 12 illustrates a percutaneous laminotomy lead that is formed of suitable flexible material without any waisted regions 50. Although material selection for
20 or construction of the platform structure 16 could be used to emulate the flexibility characteristics otherwise attainable through the use of the waisted regions 50, it may be desirable to provide a less flexible structure that simply exploits the valuable attribute of a percutaneously insertable "laminotomy" lead.

[0056] While not shown, it is contemplated that a waisted region(s) 50 could be formed in the principal planar surfaces of a platform structure of a laminotomy lead between two or more electrodes 20 so as to form thinner regions in a thickness direction. Functionally, when the contoured end of the stylet 54 of Figure 8B is then oriented substantially perpendicular to the principal planar surfaces of a stimulation lead, at least a portion of the platform structure 16 would be caused to deform outside a non-deflected plane otherwise defined by the platform structure 16. Accordingly, stimulation lead having this feature would facilitate relative upward and downward movement of the platform structure 16 during insertion. While the environment of an epidural space may not require such feature, other regions of the human body or other environments may benefit from such feature. Further yet, this feature could be combined with the earlier-described, transversely oriented waisted regions 50 to enable such a lead to be steered in two dimensions. Steering control could be accomplished with multiple stylets, each stylet including a unique contour to address a corresponding waisted region, or a single stylet "keyed" to corresponding waisted regions.

[0057] Notwithstanding the plurality of configurations of the percutaneous insertion-capable stimulation leads of the present invention, Figures 13A and 13B illustrate one embodiment of the insertion needle 200 (Figure 6) usable to insert and place any one of the above-discussed stimulation leads. The needle 200 defines an interior path 202 that ultimately receives and guides a stimulation lead 100x into an epidural space. However, at least initially, the path 202 receives a stylet 204, wherein the needle 200 and the stylet 204 combination facilitates penetration through human tissue into the patient's epidural space.

[0058] As but one example of an implantable procedure, a small incision is first made in a patient's skin using a scalpel at the desired site of insertion. Making an initial incision prevents the application of excess force to the tip of the needle 200 and further avoids the undesirable introduction of dermal matter into the epidural space. The
5 needle 200 and the stylet 204 combination is introduced through the incision at an angle that allows passage of the needle 200 between vertebral bodies. Once the distal end of the needle 200 is positioned within and opens into the epidural space, the stylet 204 is removed to allow insertion of the platform structure 16 of a stimulation lead 100x.

[0059] Given the increased surface area of the cross-section of the needle 200
10 and the stylet 204 combination (Figure 14), it is important that the stylet 204 efficiently integrate with the needle 200 (Figure 15) to provide a largely "unitary" surface that facilitates penetration through the tissue that encompasses an epidural space.

[0060] A lamitrode epidural needle having a generally rectangular passageway can be employed for the insertion of the percutaneous stimulation lead, as an example,
15 the generally rectangular passageway can have a height in the range of one to two millimeters and a width in the range of two to four millimeters, with the width to height ratio being approximate 2:1. While a needle is one type of percutaneous introduction device, there are other known percutaneous introduction devices and methods available, e.g., a dilating catheter can be employed in the form of a silicone sleeve
20 surrounding a needle for the initial insertion through the skin, with removal of the needle after the insertion of the sleeve through the skin, followed by insertion of a dilator into the hollow sleeve to expand the sleeve. The dilator can have a hollow passage for the insertion of the stimulation lead of the present invention.

[0061] While the invention has been described herein relative to a number of particularized embodiments, it is understood that modifications of, and alternatives to, these embodiments, such modifications and alternatives realizing the advantages and benefits of this invention, will be apparent to those of ordinary skill in the art having
5 reference to this specification and its drawings. It is contemplated that such modifications and alternatives are within the scope of this invention as subsequently claimed herein, and it is intended that the scope of this invention claimed herein be limited only by the broadest interpretation of the appended claims to which the inventors are legally entitled.

WHAT IS CLAIMED IS:

1. A lead capable of a percutaneous insertion comprising:

a plurality of terminals;

a plurality of conductors;

5 a plurality of electrodes; and

a body defining a paddle structure that is substantially defined by two principal opposing planar surfaces, where one of the two planar surfaces incorporates the plurality of electrodes and a conductor of the plurality of conductors electrically coupled to one terminal of the plurality of terminals and at least one electrode of the plurality of
10 electrodes, and where a greatest transverse dimension of the body is less than a corresponding interior dimension of a percutaneous introduction means, where the percutaneous introduction means is for inserting the lead through the introduction means into a human body.
2. A lead in accordance with Claim 1, further comprising a channel means extending from a proximal end of the lead to a position within the body of the lead, wherein the channel means is adapted for receiving a stylet.
3. A lead in accordance with Claim 2, wherein the body of the lead has a varying cross-sectional moment of inertia.
4. A lead capable of a percutaneous insertion having a distal end portion and a proximal end portion, the lead further comprising:

a plurality of terminals positioned at the proximal end portion;

a plurality of conductors, wherein a conductor of the plurality of conductors
5 electrically couples one terminal of the plurality of terminals with at least one electrode
of a plurality of electrodes; and

a paddle-shaped body positioned at the distal end portion, wherein the body
includes two principal opposing substantially planar surfaces, the body carrying the
plurality of electrodes on one of the two principal surfaces of the body, and where a
10 greatest transverse dimension of the body is less than a corresponding interior
dimension of a percutaneous introduction means, where the percutaneous introduction
means is for inserting the lead through the introduction means into a human body.

5. A lead in accordance with Claim 4, further comprising a channel means
extending from the proximal end portion to a position within the body of the lead,
wherein the channel means is adapted for receiving a stylet.

6. A method of placing a lead in a human, the method comprising the steps
of:

providing a lead, such lead comprising:

a body having two principal surfaces arranged opposite to one
5 another, each of such surfaces being substantially planar;

a plurality of terminals;

a plurality of electrodes positioned relative to one principal surface of the body; and

10 a plurality of conductors, wherein a conductor electrically couples one terminal of the plurality of terminals with at least one electrode;

percutaneously accessing a site proximate to a desired lead placement site through an insertion means for formation of an access passage; and

directing the lead through the insertion means to the desired lead placement site.

7. A method in accordance with Claim 6, wherein the lead further comprises a channel means extending from a proximal end of the lead to a position within the body, and this channel means is adapted for receiving a stylet, and wherein the step of directing includes a means for using a stylet within the channel means to steer the lead
5 to the desired lead placement site.

8. A method of placing a lead in a human, the method comprising the steps of:

providing a lead, such lead comprising:

5 a body having two principal surfaces arranged opposite to one another, each of such surfaces being substantially planar, and at least one flexible region;

a plurality of terminals;

a plurality of electrodes positioned relative to one principal surface of the body; and

10 a plurality of conductors, wherein a conductor electrically couples one terminal of the plurality of terminals with at least one electrode;

percutaneously accessing a site proximate to a desired lead placement site through an insertion means for formation of an access passage; and

directing the lead through the insertion means for formation of the access
15 passage to the desired lead placement site.

9. A method in accordance with Claim 8, wherein the lead further comprises a channel means extending from a proximal end of the lead to a position within the body, and this channel means is adapted for receiving a stylet, and wherein the step of directing includes a means for using a stylet within the channel to steer the lead to the
5 desired lead placement site.

10. A method in accordance with Claim 9, wherein the at least one flexible region enables a flexibility of the body to enhance steerability of the lead.

11. A percutaneous insertion system comprising:

a lead having a distal end portion and a proximal end portion comprising:

a plurality of terminals positioned at the proximal end portion,

a paddle-shaped body positioned at the distal end portion, wherein the
5 body includes two principal opposing substantially planar surfaces and at least

one flexible region, a plurality of electrodes, which are carried on one of the two principal surfaces of the body, and

10 a plurality of conductors, wherein a conductor of the plurality of conductors electrically couples one terminal of the plurality of terminals with at least one electrode of the plurality of electrodes;

a percutaneous introduction means through which the lead is passed for insertion into a human body, wherein the body of the lead has a varying transverse dimension that enables flexibility in a plane substantially parallel to the principal surfaces of the body of the lead.

12. A system in accordance in Claim 11, wherein the at least one flexible region is formed by a narrowing of the body in a transverse direction.

13. A system in accordance with Claim 11, further comprising a channel means extending from the proximal end portion of the lead to a position within the body, wherein the channel means is adapted for receiving a stylet.

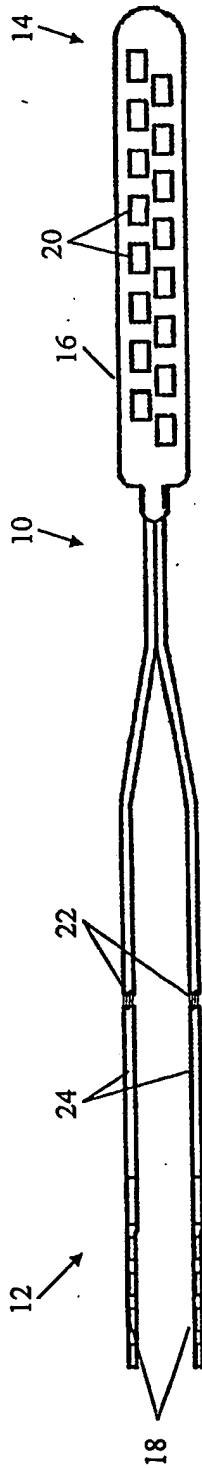


FIG. 1

Prior Art

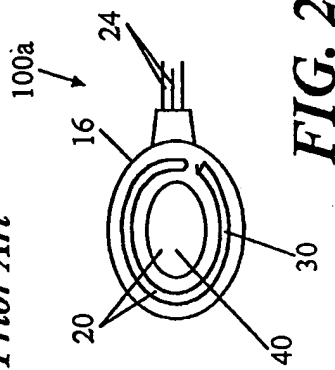


FIG. 2

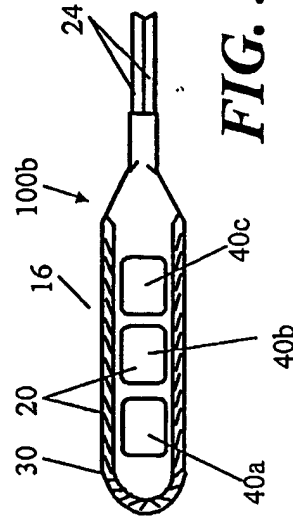


FIG. 3

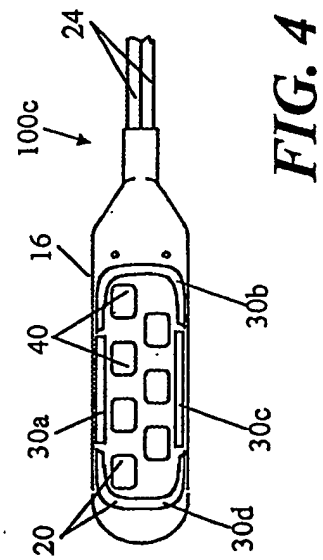


FIG. 4

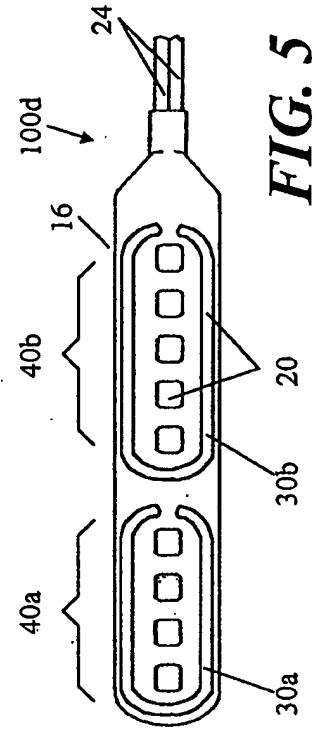
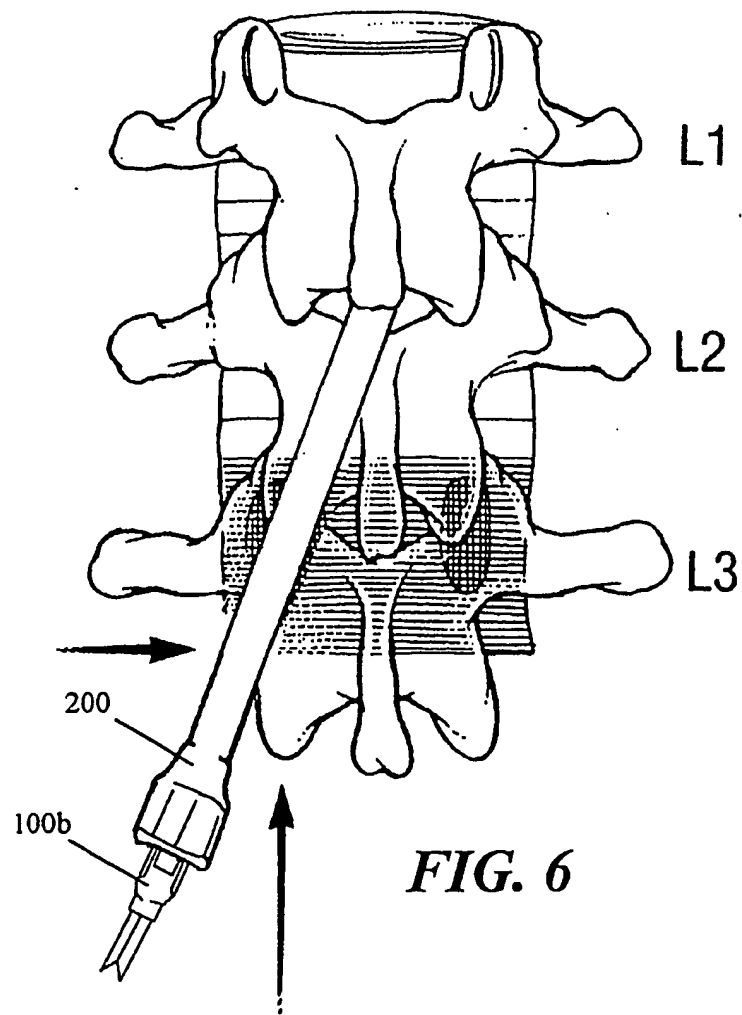
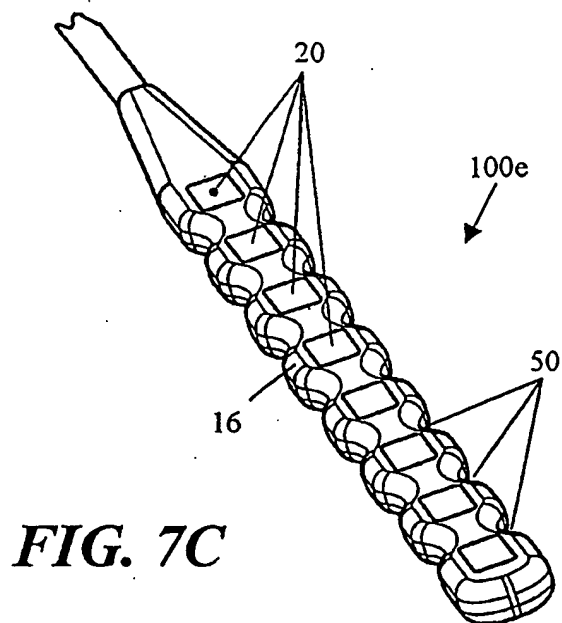
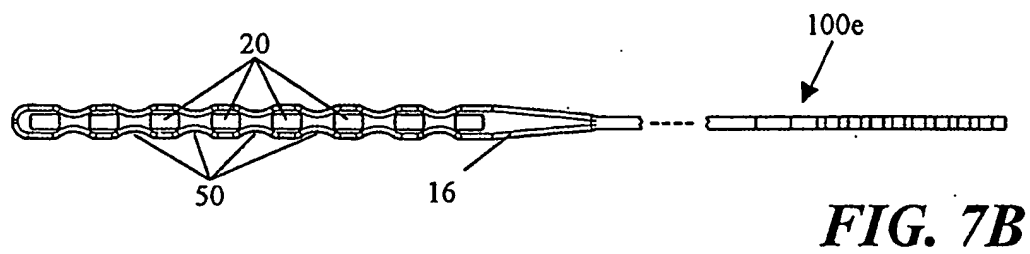
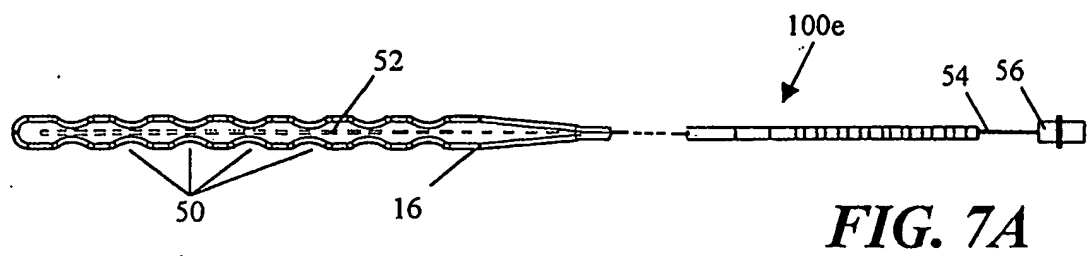


FIG. 5





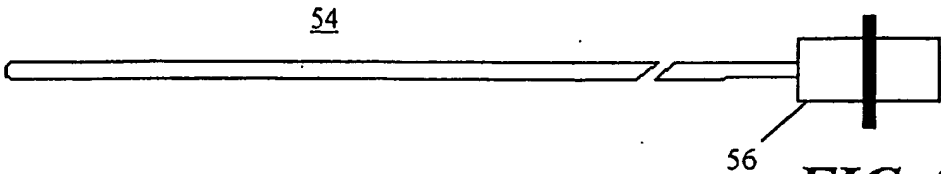


FIG. 8A

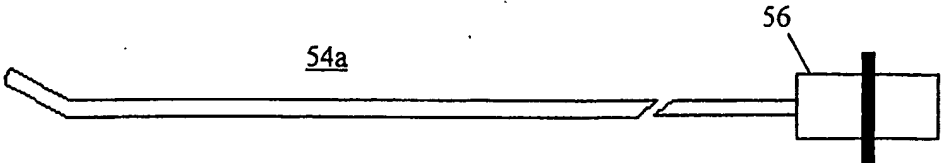


FIG. 8B

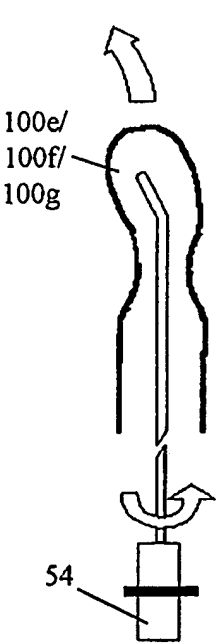


FIG. 9A

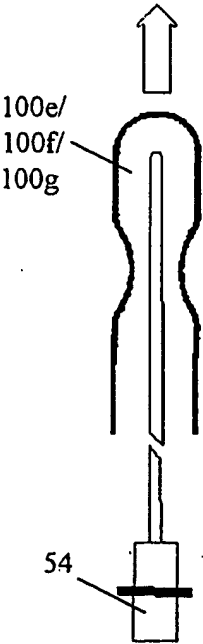


FIG. 9B

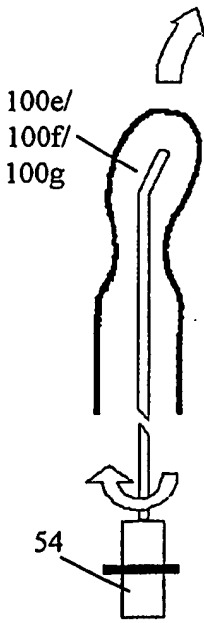


FIG. 9C

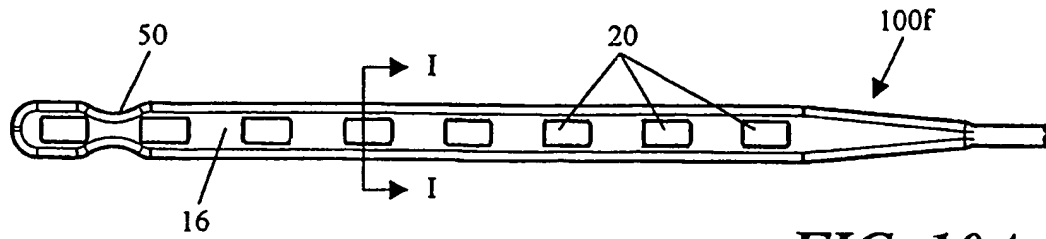


FIG. 10A

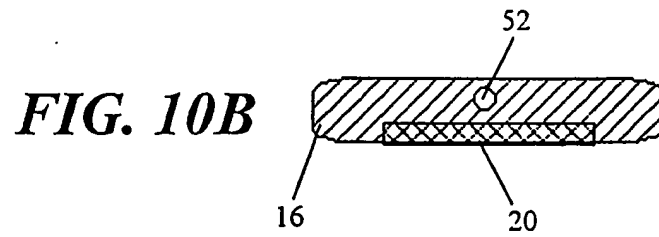


FIG. 10B

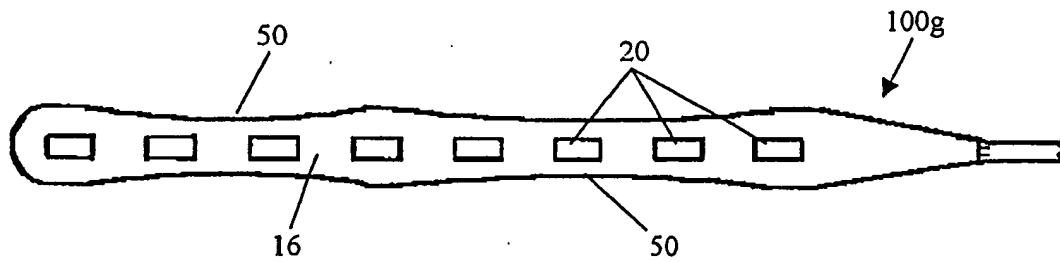


FIG. 11

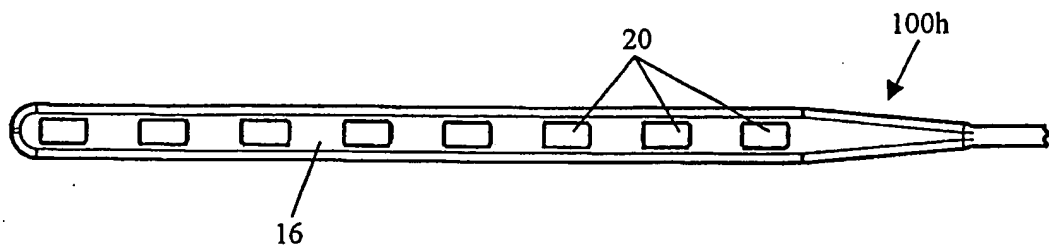


FIG. 12

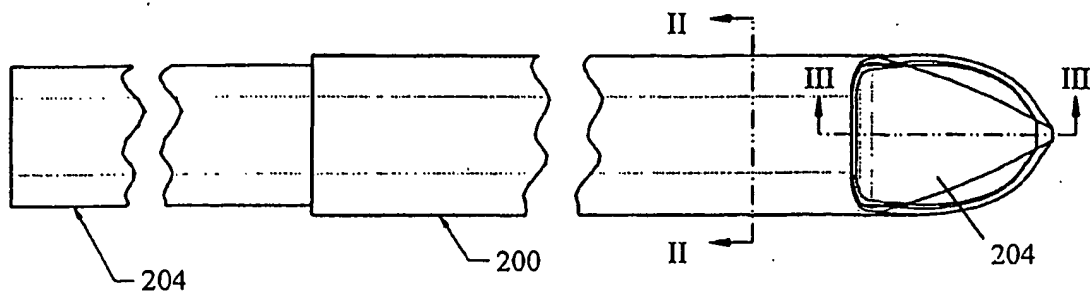


FIG. 13A

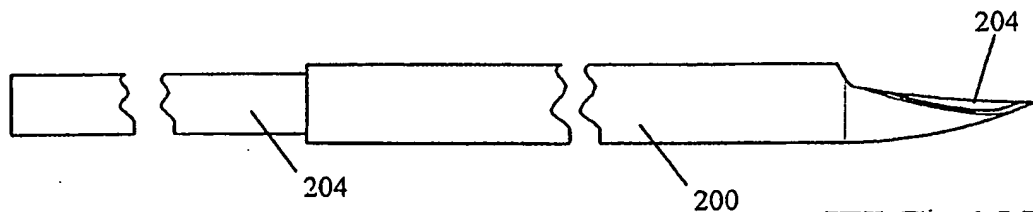


FIG. 13B

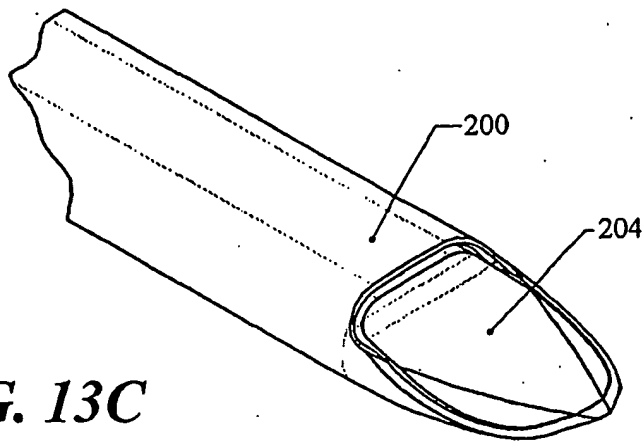


FIG. 13C

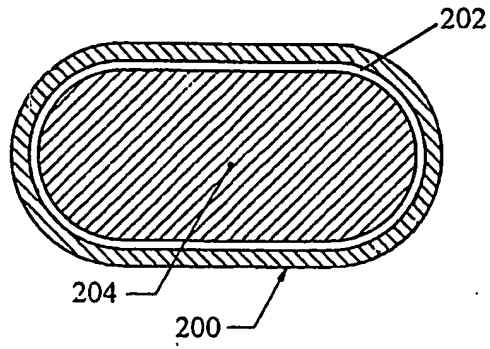


FIG. 14

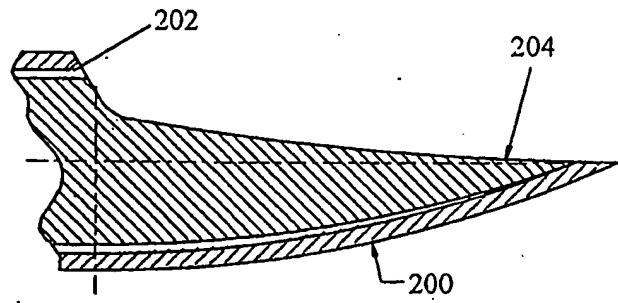


FIG. 15

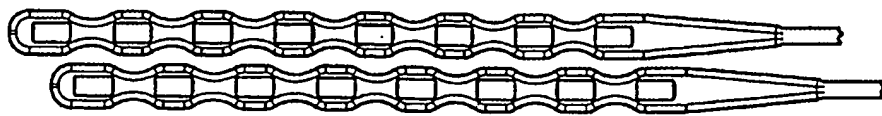


FIG. 16

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/24387

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61N1/05 A61B5/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61N A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 048 271 A (MEDTRONIC INC) 2 November 2000 (2000-11-02) abstract; figures 2,3,7,11,12 paragraph '0001! - paragraph '0018! paragraph '0022! - paragraph '0025! ---	1-5, 11-13
P,X	US 2002/022873 A1 (DREES SCOTT F ET AL) 21 February 2002 (2002-02-21) abstract; figures 1,3,4,5,7A,7B,7C paragraph '0015! - paragraph '0020! paragraph '0038! - paragraph '0076! ---	1-5, 11-13
P,X	WO 02 13903 A (ADVANCED NEUROMODULATION SYSTE) 21 February 2002 (2002-02-21) abstract; figures 1,3-5 page 4, line 17 -page 5, line 5 page 5, line 19 -page 11, line 18 --- -/--	1,4,11, 12

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

27 September 2002

Date of mailing of the international search report

16/10/2002

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INTERNATIONAL SEARCH REPORT

Int'l Application No

PCT/US 02/24387

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 862 925 A (MEDTRONIC INC) 9 September 1998 (1998-09-09) abstract; figures 3,8 column 4, line 14 - line 28 column 5, line 27 - line 39 ----	1-5, 11-13
A	EP 0 580 928 A (ARIES S R L) 2 February 1994 (1994-02-02) abstract; figures 1,2 ----	1-5, 11-13
A	US 5 919 220 A (MEYER JOERG-UWE ET AL) 6 July 1999 (1999-07-06) abstract; figure 1 ----	1-5, 11-13
A	EP 0 215 726 A (UNIV MELBOURNE) 25 March 1987 (1987-03-25) abstract; figures 1-3 page 2, line 12 - line 20 page 4, line 28 -page 5, line 20 page 5, line 24 -page 6, line 6 page 6, line 12 - line 18 ----	1-5, 11-13
A	US 4 832 051 A (JARVIK ROBERT K ET AL) 23 May 1989 (1989-05-23) abstract; figures 20-23 column 10, line 31 -column 11, line 13 -----	1-5, 11-13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 02/24387

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

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because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

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2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 02/24387

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
EP 1048271	A	02-11-2000	US	6249707 B1	19-06-2001
			EP	1048271 A2	02-11-2000
US 2002022873	A1	21-02-2002	AU	6537801 A	25-02-2002
			WO	0213903 A2	21-02-2002
WO 0213903	A	21-02-2002	AU	6537801 A	25-02-2002
			WO	0213903 A2	21-02-2002
			US	2002022873 A1	21-02-2002
EP 0862925	A	09-09-1998	US	5957965 A	28-09-1999
			EP	0862925 A2	09-09-1998
EP 0580928	A	02-02-1994	EP	0580928 A1	02-02-1994
			US	5374285 A	20-12-1994
US 5919220	A	06-07-1999	DE	4433111 A1	21-03-1996
			DE	59507542 D1	03-02-2000
			WO	9608290 A1	21-03-1996
			EP	0843574 A1	27-05-1998
			JP	10505762 T	09-06-1998
EP 0215726	A	25-03-1987	AU	582264 B2	16-03-1989
			AU	6114086 A	26-02-1987
			EP	0215726 A2	25-03-1987
			JP	62090154 A	24-04-1987
US 4832051	A	23-05-1989	NONE		

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